

animal subjects in research conducted at that field installation and for ensuring compliance with this rule at that field installation.

(f) *Investigator* is any person who uses or proposes to use live animal subjects in NASA-supported activities, e.g., receives funds, salaries, or support under a grant, award, agreement, contract, or direct employment by NASA, or the use of any NASA facilities, aircraft, or spacecraft for the purpose of carrying out research, tests, or experiments using animal subjects.

(g) *PHS Assurance* is a document prepared by an awardee institution assuring its compliance with PHS Policy.

(h) *Research of Flight Program Manager* is the NASA Headquarters manager of each program in which NASA has a manifest interest.

(i) *Supported* pertains to activities either funded in part or in whole by NASA or an approved activity that is not funded by NASA but that utilizes NASA facilities, including spacecraft and aircraft.

(j) *Veterinarian* is the NASA attending veterinarian, a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, has received training and/or experience in the care and management of the species being attended, and who has direct or delegated authority and responsibility for activities involving animal subjects at the NASA field installation.

**§ 1232.104 Implementation procedures by non-NASA institutions.**

(a) *Proposal Information.* No animal subjects may be utilized unless a proposal justifying and describing their use is submitted to NASA for approval. The required proposal information is outlined in the PHS Policy (IV.D.1.a.–e.).

(b) *Proposal Approval by the Institutional ACUC.* Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has

been reviewed in accordance with the PHS Policy (IV.C.) and approved by the appropriate ACUC at the participating institution.

(c) *Proposal Approval for Flight Experiments.* In addition to the institution's ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the Ames Research Center (ARC) ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the Human Research Policy and Procedures Committee (HRPPC) at the Johnson Space Center (JSC). Animal activities utilizing the facilities of any NASA field installation are also subject to approval of that field installation's ACUC (§1232.105(d)).

(d) *Institutions with PHS Assurance on File.* The institution, by an approved or provisionally acceptable Assurance on file at the NIH Office for Protection from Research Risks (OPRR), Department of Health and Human Services (HHS), assures NASA that it will comply with the PHS Policy. The Assurance file number must be included in the research proposal submitted to NASA.

(e) *Institutions with no PHS Assurance on File.* Proposals from institutions without an approved Assurance on file with the NIH OPRR will first be peer-reviewed for scientific merit. If the proposed research is deemed worthy of support, NASA will arrange for a special Assurance to be negotiated by the Director, Life Sciences Division, NASA Headquarters. The arrangements for a special Assurance review by NIH should be undertaken in consultation with the NASA representative to the Interagency Research Animal Committee (IRAC) and will be handled on a case-by-case basis.

(f) Foreign institutions must comply with the PHS Policy (see Section II Of PHS Policy) and this rule before being supported by NASA for any activities involving animal subjects.